

The following corrections or additions to the January 2000 list were published in the Federal Register in June 2000.

Supplemental Approvals

NADA Number: 141-099

This supplemental application provides for topical use of a 0.5% moxidectin solution on dairy cattle of breeding age for treatment and control of infections and infestations of certain internal and external parasites. In addition, the regulations are amended to establish a tolerance for moxidectin residues in milk.

Trade Name: Cydectin® Pour-On
Ingredients: Moxidectin
Sponsor: Fort Dodge Animal Health, Division of American Home Products Corporation
Approval Date: November 2, 1999
Status: Over-the-counter
Route: Topical
Species: Beef and dairy cattle
Drug Form: Solution
Concentration: 0.5% (5 milligrams per milliliter)
Indications: For the treatment and control of various roundworms, lungworms, grubs, biting and sucking lice, horn flies, and mange mites.
Tolerance: 21CFR 556.426: Tolerances of 200 parts per billion (ppb) for parent moxidectin (marker residue) in liver (target tissue) and 50 ppb in muscle. A tolerance of 40 ppb is established for parent moxidectin in milk. The ADI has been established at 0.004 milligrams of moxidectin per kilogram of body weight per day.
Withdrawal: Zero days
Patent Number: 4,916,154
Exclusivity: 3 years
Expiration Date: April 10, 2007

21CFR 524.1451 and 556.426

Change of Sponsor Address

From: Medicis Dermatologics, Inc.
4343 East Camelback Rd, Suite 250
Phoenix, AZ 85018-2700
Labeler code: 099207

To: Medicis Dermatologics, Inc.
8125 North Hayden Rd.
Scottsdale, AZ 85258

From: ADM Animal Health & Nutrition Division
P.O. Box 2508
Fort Wayne, IN 46801-2508
Labeler code: 017519

To: ADM Animal Health & Nutrition Division
1000 North 30th St., Box 1C
Quincy, IL 62305-3115

Suitability Petition Action

Number: 00P-1342/CP1
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug , pyrantel pamoate, which differs from the pioneer product, Strongid® P, Pfizer Inc., NADA 129-831, by the following characteristic: The generic product will contain a different concentration, 19.13% w/w active ingredient whereas the pioneer product contains 15.25% w/w active ingredient.
Action: Filed on June 15, 2000.